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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/334,163	06/16/1999	BRUCE NAGEL	MPS-411XC1	5018

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/12/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/334,163

Applicant(s)

NAGEL, BRUCE

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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STATUS OF THE APPLICATION

The Amendment filed February 7, 2002, paper no.13, has been entered.

Claims 1, 4, 6, 10 and 16 are newly amended.

Claims 1-11 and 16 are pending.

The following amendments to the specification are acknowledged: replacement of the paragraph found on page 9 lines 16-21.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-11 and 16, under 35 U.S.C. 112, first paragraph, for enablement, for the lack of a deposit for seed strain LS288, is withdrawn in light of Applicant's deposit of seed strain LS288.

Claims 1-11 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to corn seeds derived from the high oleic line "Holeisyn". Since the high oleic line "Holeisyn" is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the high oleic line "Holeisyn" is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the high oleic line "Holeisyn", and it is not apparent if such a plant is readily available to the public. If a deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and

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registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

For each deposit made pursuant to these regulations, the specification shall be amended to contain (see M.P.E.P. § 1.809):

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

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(4) The name and address of the depository.

Claims 1-11 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "LS1498", "LS288" and "LS0417" corn seed and plants, does not reasonably provide enablement for corn seed or plants derived from the high oleic line "Holeisyn". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to corn seed and plants derived from the high oleic line "Holeisyn" having a mean saturate content of less than about 7.0%, a mean oleic acid content of at least 64.9%, and a mean linoleic acid content of 27.4%. The claims are also drawn to a method for producing low saturate corn material utilizing said plants and seed.

The specification discloses three corn lines, "LS1498", "LS0417" and "LS288", which were made by EMS mutagenesis of the pollen of F2 plants derived from a cross of two high oleic corn lines from the source population "Holeisyn". The specification also teaches that the seed oil from the three exemplified lines was lower in total saturates and linoleic acid, and higher in oleic acid, than the elite line "OQ144". (page 8 Table 1). The specification does not disclose assemblages of seed comprising seed from other lines wherein the mean fatty acid profiles are as claimed. The specification does not disclose that the three lines were obtained by a routine and repeatable method without undue trial and error experimentation. The specification does not disclose, and the prior art does not teach, the fatty acid profile characteristic of high oleic corn lines from the source population "Holeisyn". The specification does not disclose, and the prior art does not teach, what relationship, if any, exists between the elite line "OQ144" and high oleic corn lines from the source population "Holeisyn". It is unclear what differences, if any, exist between the fatty acid profiles of

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the three corn lines, "LS1498", "LS0417" and "LS288", and the fatty acid profiles of the parental lines from which they are derived. Applicant provides no guidance to indicate that the use of Holeisyn increased the predictability of obtaining mutant plants with the claimed fatty acid profiles. In the absence of such guidance, undue trial and error experimentation would be required to make other mutant plants and seeds derived from the high oleic line "Holeisyn" that would have the fatty acid profile of the claimed invention. Furthermore, the specification does not disclose the identification of the gene or genes that must be modified in or introduced into a corn plant to produce the claimed effect. Mutation breeding randomly introduces mutations into the genome, cannot be specifically directed to alter a particular gene or group of genes, and can result in the introduction of deleterious as well as desirable mutations. Consequently, mutation breeding to obtain plants with a specified phenotype is also highly unpredictable.

Given the lack of guidance in the specification regarding the frequency and heritability of the claimed fatty acid profile, the complex nature of the invention, the unpredictability of selecting a particular fatty acid profile through conventional breeding, the unpredictability of altering a particular fatty acid profile through EMS mutagenesis, and the breadth of the claims which encompass any corn plant or seed derived from the high oleic line "Holeisyn" having the claimed fatty acid profile, undue experimentation would be required of the skilled to make and/or use the invention in its full scope.

The rejection of claims 4 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of cultivar names absent any deposit accession number, is withdrawn in view of Applicant's amendment of the claims to include the recitation of deposit accession number for line LS288.

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The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "assemblage of corn seeds", is withdrawn in light of Applicant's argument that the ordinary artisan could analyze any assemblage of seeds to determine whether they meet the limitations of the recited claims.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
March 6, 2002



**AMY J. NELSON, PH.D
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